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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,412	04/15/2004	Sabine Behrends	Serie 6292	9359

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,412	BEHRENDS ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-25 and 28-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25 and 28-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 December 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 23-25, 28-33, 35-40, 42, 43, 45-65, 67-70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. (US 5,539,001) in view of Hachmann et al. (US 5,646,105) and Tu et al. (WO 92/09309).

With respect to claims 23-25, 28-33, 35-37, 59, 63, 65, 69, 70, and 72, Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and a glycerol ether having a C_{6-22} alkoxymethyl group. See Abstract and Formula II (col.1, lines 50-57). The composition disclosed by Waldmann-Laue et al. may be an aqueous or anhydrous solution. See col.2, lines 6-10. The aromatic alcohol may be benzyl alcohol (an arylalkanol) or phenylethanol (an arylalkanol). See col.2, lines 11-14. The composition may further

include a salt, magnesium sulfate (col.3, line 30) and is effective against bacteria and fungi (col.3, lines 44-48 and Examples). The ether to alcohol weight ratio is 1:9, which converts to 0.11. See Abstract. Furthermore, Waldmann-Laue et al. discloses treatment at ambient temperatures.

Hachmann et al. discloses a disinfectant composition containing a disinfectant in combination with an aromatic alcohol as a solubilizer. The ratio of aromatic alcohol to disinfectant is about 1:0.5 to 1:0.07. See col.1, lines 49-53. It would have been obvious to increase the amount of alcohol in the composition of Waldmann-Laue et al. as Hachmann et al. teaches that this ratio of alcohol is effective in promoting stability of the disinfectant compositions at low temperatures and for extended periods of time. See col.1, lines 54-58.

Tu et al., however, teaches a method of sterilization of hard surfaces using a mixture of a glycidyl ether and an aromatic alcohol. Tu et al. further discloses that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to increase and optimize the treatment temperature, an established result effective variable, based upon the particular concentration of sterilant used and the amount of contamination present, to both increase the percent kill and to reduce the treatment time.

As to claims 39 and 40, Waldmann-Laue et al. fails to teach a method of application on hard surfaces. Tu et al., however discloses that the hard surface may be submerged in the disinfectant for sterilization (page 7, lines 22-24). As submerging

(dipping) the hard surface promotes contact and wetting of the entire surface with the disinfectant, it would have been obvious in the method of Waldmann-Laue et al..

With respect to claim 42, Waldmann-Laue et al. teaches the disinfection of "hard surfaces" but does not enumerate any specific surfaces. However, one of ordinary skill in the art at the time of the invention would have recognized the term "hard surfaces" to includes at least one of metal, glass, plastic, and ceramic, as known in the art.

With respect to claim 43, Waldmann-Laue et al. is silent with respect to disinfecting a medical instrument. However, Tu et al. teaches that medical instruments can be successfully sterilized using organic ether compositions. Thus, it would have been obvious to one of ordinary skill in the art to use the composition of Waldmann-Laue et al. to sterilize medical instruments in the manner of Tu et al.

As to claims 45-47, Waldmann-Laue et al. fails to teach a treatment time. Tu et al. discloses that "[t]he optimum sterilization time is related to the quantity of microorganism present and the level of sterility assurance desired. Consequently, the time can be varied according to needs." See page 8, lines 1-4. In view of the teachings of Tu et al., it would have been obvious to optimize treatment time according to other result effective variables, such as concentration of disinfectant, treatment temperature and the quantity of microorganisms present.

With respect to claims 48-58, Waldmann-Laue et al. discloses that the antimicrobial diol (glycerol ether) and the alcohol are present in a ratio of 9:1 to 1:9 (claim 1). This means that the glycerol either is present in an amount of 10-90% of the composition before any dilution and the alcohol is present in an amount from 90-10% before any dilution. It is deemed obvious to one of ordinary skill in the art to optimize

the relative amounts of the glycerol ether and the alcohol for the particular use of the composition. Moreover, one would have found it obvious to also optimize the dilution amount for the same reasons. The optimization of concentration, a result effective variable, is readily determined through routine experimentation and is deemed obvious in the absence of unexpected results.

With respect to claim 60, while Waldmann-Laue et al. is silent with respect to the treatment pH, it would have been obvious to maintain the pH near neutral in order to avoid the corrosive effects of a strong basic or acidic solution.

As to claims 61-62, Waldmann-Laue et al. teaches generally C_{6-22} alkyls which include both straight and branched chains. Moreover, a chain length of 6 to 22 carbon atoms in the alkoxymethyl group encompasses the claimed ethers and thus, they are rendered obvious by the disclosure of Waldmann-Laue et al..

With respect to claims 64, 67, and 68, although Waldmann-Laue et al. teaches the use of an aromatic alcohol as an essential part of the composition, an arlyoxyalkanol is not disclosed. However, Hachmann et al. evidences the functional equivalence of phenoxypropanol and phenoxyethanol with benzyl alcohol. See Table; col.3, lines 45-60. Thus, it would have been obvious to substitute one for the other in the invention of Waldmann-Laue et al..

4. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. in view of Hachmann et al. and Tu et al. as applied to claim 23 above, and further in view of Langford (US 5,906,802).

The combination of Waldmann-Laue et al. with Tu et al. discloses the use of elevated temperatures but does not teach using an elevated pressure. Langford discloses

that using alternating cycles of pressure and suction, assists with the cleaning action and assures that any sterilant is forced throughout the medical instrument. See col.8, lines 55-59. Since the combination of Waldmann-Laue et al. with Tu et al. teaches the sterilization of medical instruments, it would have been obvious to apply the method of cyclic pressurization of Langford to method of the combination.

5. Claims 41 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al., Hachmann et al., and Tu et al. as applied to claims 23 and 69 above, and further in view of Saud et al. (US 2004/0001797).

With respect to claim 41, Waldmann-Laue et al. does not teach atomizing the composition. Saud et al. discloses a disinfecting composition containing a glycerol ether in combination with an alcohol. The composition may be dispensed from a spray bottle (i.e. atomized). See paragraph [0054]. As atomization is an efficient means of providing even coverage of a surface, it would have been an obvious means of dispensing the composition of Waldmann-Laue et al..

As to claim 71, Waldmann-Laue et al. is silent with respect to triclosan within the composition. Saud et al. teaches a disinfecting composition containing a glycerol ether in combination with an alcohol. The composition may additionally include Triclosan to further improve the disinfecting action (paragraph [0037]). For this reason, it would have been obvious to include Triclosan in the composition of Waldmann-Laue et al..

6. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al., Hachmann et al., and Tu et al. as applied to claim 43 above, and further in view of Miner et al. (US 6,096,348).

The combination of Waldmann-Laue et al. with Tu et al. teaches the treatment of hard surfaces but not the treatment of an endoscope. Miner et al. discloses it was known in the art at the time of the invention that medical instruments such as endoscopes are particularly hard to sterilize due to their sensitivity to high temperatures and pressures. As the sterilant of Waldmann-Laue et al. is effective at low temperatures, it would have been obvious to use for the sterilization of endoscopes.

7. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al., Hachmann et al., and Tu et al. as applied to claim 63 above, and further in view of Eggensperger et al. (US 5,393,789).

Although Waldmann-Laue et al. teaches the use of an aromatic alcohol as an essential part of the composition, an oligoalkanol aryl ether is not disclosed. Eggensperger et al. teaches a surface disinfectant including an antimicrobial in combination with an aromatic alcohol. Suitable aromatic alcohols include the arylalkanols (phenyl ethanol, phenyl propanol, benzyl alcohol) of Waldmann-Laue et al. as well as oligoalkanol aryl ethers. See col.2, lines 41-68. As the disclosure of Eggensperger et al. teaches the functional equivalence of these three types of aromatic alcohols, one of ordinary skill in the art would have found it obvious to substitute one for another in the composition of Waldmann-Laue et al. and to have an expectation of success when doing so.

8. Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,906,802) in view of Waldmann-Laue et al..

Langford teaches a method of sterilizing a medical instrument wherein the instrument is first cleaned with a detergent to remove bioburden therefrom, disinfected with a liquid or gas sterilant, rinsed with sterile water, and then dried. See col.1, lines 40-52; col.2, lines 35-42; col.3, lines 16-19; col.5, lines 25-26. Although Lanford is silent with respect to a disinfection time, it is deemed obvious to optimize the time the sterilant is in contact with the instrument dependent upon the concentration of sterilant, the temperature of the sterilant, and the amount of contamination present. It is noted that all of contact time, temperature, and concentration are result effective variables. Normally, the change or optimization of a result effective variable would be considered an unpatentable modification in the absence of unexpected results. Langford does not disclose use of an alkyl glycerol ether as the sterilant. Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and a glycerol ether having a C_{6-22} alkoxymethyl group. Since the sterilant of Waldmann-Laue et al. is effective at low-temperatures, it would have been an obvious choice for the sterilization of the thermolabile medical instruments of Langford. With respect to "pre-cleaning" (i.e. rinsing) the instrument with water before the initial step of cleaning, Langford discloses that the method employs several cycles of washing, either with or without a detergent, in order to completely remove the bioburden prior to sterilization. See col.1, lines 47-51.

9. Claims 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford and Waldmann-Laue et al. as applied to claim 73 above, and further in view of Tu et al..

Langford fails to disclose a treatment temperature. Tu et al. teaches in a method of sterilization that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-33, 37, and 51-53 of copending Application No. 10/445,715 in view of Tu et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims substantially encompasses the subject matter of the instant claims. The co-pending claims do not claim a treatment temperature. Tu et al., however, teaches in a method of sterilization that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 73-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67-73, 75, and 80 of copending Application No. 10/825,266. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the copending application and the instant claims differ only in that the instant claims recite "thermal" disinfection. However, as no particular temperature is claimed, the copending claims read on the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments filed 21 December 2007 have been fully considered but they are not persuasive.

14. Applicant's arguments with respect to claims 23-25 and 28-72 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant argues on page 18 of the Response that neither Langford nor Waldmann-Laue et al. disclose thermochemical treatment for 1-20 minutes. With respect the claims 73 and 74, no temperature is recited so 'thermochemical' is interpreted to occur at room temperature. Moreover, in the absence of unexpected results, it is submitted that the optimization of treatment time, a known result effective variable, is within the purview of one of ordinary skill in the art.

16. Furthermore, as to applicant arguments on page 19 of the Response that Waldman-Laue et al requires greater than 3 days to achieve sterilization, the examiner remains unconvinced that the difference in treatment time between Waldmann-Laue et al. and the instant invention is anything more than a difference initial treatment parameters since the composition of Waldmann-Laue et al. is so similar to that claimed.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh McKane/
Primary Examiner, Art Unit 1797

elm
3 March 2008